



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/587,023

01/09/2007

Rene Bernards

BJS-620-445

9239

23117 7590 01/05/2010
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

01/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,023	Applicant(s) BERNARDS ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/21/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 09/21/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 03/19/2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 09/21/2009, claims 1-8 and 12 are pending in the application. Claims 1-4 are currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 09/21/2009 is in compliance with 37 CFR 19.7. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Response to Applicant's Arguments

Claim Rejections - 35 USC § 101 and 35 USC § 112

The rejection of claims 9-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is moot as these claims have been canceled.

The rejection of claims 9-11 under 35 U.S.C. 101 is moot as these claims have been canceled.

Claim Rejections - 35 USC § 112

The rejection of claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn as the claims have been amended.

The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

Applicant's arguments filed 09/21/2009 have been fully considered but they are not persuasive. Applicant submits the recitation of HDAC inhibitors in the claims is adequately supported by the specification. Applicant argues the specification exemplifies four broad chemical classes of HDAC inhibitors and the fact that it was known that all of these compounds act as HDAC inhibitors at the time of filing there is no reason to doubt that the use of any of these compounds with a PRAME inhibitor would provide the same results in terms of tumor treatment as exemplified in the specification.

In response, the nature of the invention relies upon inhibiting PRAME with a RNAi in combination with any HDAC inhibitor in a subject such that treatment of a tumor occurs. The instant specification does not exemplify all known HDAC inhibitors, such as nucleic acid inhibitors, antibodies or other small molecule or chemical inhibitors which

Art Unit: 1635

are encompassed by the breadth of the claims nor does the specification exemplify or provide guidance for treatment of any tumor type with RNAi in combination with any HDAC inhibitor in a subject. As stated previously, McCarthy et al. (Nature Reviews 2005) reviews the state of the art regarding the link between PRAME over-expression and tumor cell proliferation. McCarthy acknowledges the work of Applicant in showing that knock-down in expression of PRAME using a shRNA restored apoptosis in melanoma cells in vitro but cautions that the use of PRAME as a therapeutic to treat cancer in a subject requires further investigation. Furthermore, McCarthy indicates that treatment of cells with a HDAC inhibitor trichostatin A did not affect expression of PRAME. Thus it is clear that the state of the art questions the inhibition of PRAME as a therapeutic for treatment of tumors without further work and illustrates that all inhibitors of PRAME are not capable of reducing the expression of PRAME.

While the instant specification do in fact show HDAC inhibitors, the specification fails to provide enablement for a method of treating all cancer types using RNAi targeted to PRAME in combination with any HDAC inhibitors known or yet to be discovered. At best, the prior art at the time of the instant invention invites further experimentation to find a treatment for any tumor type in a subject comprising administration of a siRNA targeted to PRAME along with an inhibitor of HDAC.

Applicant further argues that the reference Epping et al. provided with the IDS filed 09/21/2009 provide evidence that all of the above classes of HDAC inhibitors act in the same way with respect to PRAME. This evidence does not provide sufficient evidence of the state of the prior art at the time of filing sufficient enough to enable any

Art Unit: 1635

person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reference is a reference by the current inventors and was published in 2007, before the earliest priority date of the current invention. Thus, as stated above, this does not provide evidence of the state of the art at the time of filing.

The specification does provide guidance for a method of decreasing A375 melanoma cell proliferation in vitro using a siRNA targeted to a gene encoding PRAME wherein the cells were cultured with a HDAC inhibitor PXD10. However because the claims are drawn to any HDAC inhibitor in combination with an RNAi of PRAME to treat any tumor type in a subject, there is no guidance in the specification that would be considered enabling for the breadth of the claimed subject matter and the working embodiment not predictive of the invention as claimed. Without further guidance, one of skill in the art would have to practice a substantial amount of trial and error experimentation, an amount considered undue and not routine, to practice the instantly claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1635

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact Tracy Vivlemore at 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635

Search Notes (continued)

Application/Control No.

10/587,023

Examiner

KIMBERLY CHONG

Applicant(s)/Patent under
Reexamination

BERNARDS ET AL.

Art Unit

1635

SEARCHED

Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED

Class	Subclass	Date	Examiner

**SEARCH NOTES
(INCLUDING SEARCH STRATEGY)**

	DATE	EXMR
updated	12/29/2009	KC